



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

72

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,160	04/12/2005	Boris Y Shekunov	FER-14857.001.001	4722
7609	7590	03/31/2006	EXAMINER	
RANKIN, HILL, PORTER & CLARK, LLP			EBRAHIM, NABILA G	
925 EUCLID AVENUE, SUITE 700			ART UNIT	
CLEVELAND, OH 44115-1405			PAPER NUMBER	

1618

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/531,160	SHEKUNOV ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 5-10, 12-17, 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Subramaniam et al. US 5,874,029 (hereinafter "Subramaniam").

Subramaniam teaches a method and an apparatus useful for the production of microparticles and nanoparticles.

The steps are:

Adding a solvent to a solute forming a mixture.

Adding the mixture to the SCF (which is a non-solvent)

Getting the particles out of the solute. (see abstract)

The invention can be used in the pharmaceutical, food, chemical, electronics, catalyst, polymer, pesticide, explosives, and coating industries, all of which have a need for small-diameter particles (abstract). The method comprises solutes such as drug, polymer, and/or excipient materials are solubilized. The supercritical antisolvent used is supercritical carbon dioxide (col. 6, lines 27, and 28), also a trifluoromethane is used (claim 12), which is encompassed by fluorocarbons recited in the current application, and poly-lactide glycolide copolymers (claim 22).

Subramaniam discloses the limitation recited in claim 8 regarding functional group of portion that is SCF-philic and SCF-phobic since the current specification discloses in paragraph [0015 and 0027] teaches that any compounds that comprise both SCF-philic groups, which make the compound soluble in SCF, and SCF-phobic groups, which have an affinity or attraction to the nuclei of the material(s) formed during the precipitation step, can be employed as growth retardant compounds. Examples of growth retardant compounds for use with supercritical carbon dioxide (SC-CO₂) include fluorocarbons. Accordingly, Subramaniam discloses a trifluoromethane, which is encompassed by the group of fluorocarbons. In addition the limitation recited in independent claim 15 of the instant application regarding expanding the SCF solution across a pressure drop below the critical pressure of the SCF whereby the SCF decompresses and causes supersaturation and nucleation of particles comprising the solute material, said particles having a smaller size and a reduced amount of agglomeration than if no growth retardant compound was present. Subramaniam discloses that following the drying period, the pressure is decreased to atmospheric level (col. 9, lines 11-24). Furthermore Subramaniam teaches that accurate pressure control is essential in the highly compressible near-critical region. Pressure fluctuations in this region have a strong effect on the level of expansion of the organic solution and thus on the level of supersaturation and nucleation (col. 9, 25-29, col. 5, line 40, 41 and example 1).

Conclusion: claims 1-3, 5-10, 12-17, 19-21 are anticipated by Subramaniam.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Subramaniam et al. US 5,874,029 in view of Tarara et al US 20030064029 (hereinafter "Tarara").

Subramaniam has been discussed above.

Subramaniam is deficient in disclosing growth retardant as sugar acetate, fluorocarbons or block polymers.

Tarara discloses engineered particles that may be used for the delivery of a bioactive agent to the respiratory tract of a patient. Tarara produces the particulates under supercritical conditions [0088]. The patent discloses the use of block copolymers

Art Unit: 1618

[0056], polymer resins of ethylene-vinyl acetate, ethylene-acrylic acid [0063], polycationic materials such as polyacrylic acid [0066], and polyethylene glycol [0057].

Accordingly, it would have obvious to a skilled man in the art to expand the teachings of Subramaniam and add the block polymers recited by Tarara since Tarara is producing fine particles for respiratory tract use, it would make a good motivation to the artisan to combine and produce a particulate drug using supercritical fluid to obtain pharmaceutical particles for use in the respiratory tract.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-13, 15, and 16 of copending Application No. 10/534,665.

Claims of application '665 recite the steps of mixing a solute in a solvent, contacting the solution with a liquefied gas (carbon dioxide), expanding the mixture to form droplets, and extracting the solvent to get the particles. The process includes sugars, or stabilizers, and the particles size range recited is within 0.05 to one micron (the ration recited in the current application is less than 10 micron and more than 300 nm which encompass the range recited in '665). Thus the instant claims are fully encompassed by the claims of the copending application.

This is a provisional obviousness-type double patenting rejection.

4. Claims 1-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 9-12, and 14-15 of copending Application No. 10/789422.

Application '422 recites a method of producing particles in which the steps are providing a supercritical fluid (carbon dioxide), two solvents, one is soluble in the SCF, the other is substantially insoluble in the SCF and partially soluble in or miscible with the first solvent and a solute (active agent) which is soluble in the first solvent and is substantially insoluble in the second solvent and the supercritical fluid. Then contacting the two solvents with solute, then contacting the solution with SCF then precipitate the solute to extract the particles form the solvents. The process may include an excipient and the targeted particle size is between 10 micron and 10 nm (the range overlaps with the instant application disclosure). Thus the instant claims are fully encompassed by the claims of the copending application.

This is a provisional obviousness-type double patenting rejection.

Correspondence

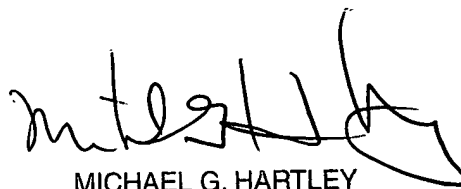
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

3/20/06


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER